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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/390,846	09/14/1999	JACOBUS JOHANNES KOK	I/95150-US/D	7646

31846 7590 04/29/2005

AKZO NOBEL PHARMA PATENT DEPARTMENT
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EXAMINER	
MINNIFIELD, NITA M	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 04/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/390,846	KOK ET AL.	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,11,13,19 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,11,13,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. attached
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicants' amendment filed February 8, 2005 is acknowledged and has been entered. Claims 3-10, 12, 14-18 and 21-26 have been canceled. Claims 1 and 11 have been amended. Claims 1, 2, 11, 13, 19 and 20 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments with the exception of those discussed below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Rejections under 112, 1st paragraph and 112, 2nd paragraph have been withdrawn in view of the cancellation of claims and/or amendment to the claims.

4. Claims 1, 2, 11, 13, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Shirley, 1975, Parasitology, 71:369-376.

The claims are drawn to an isolated protein represented by SEQ ID NO: 2 from *Eimeria acervulina*, and vaccines comprising the protein in pharmaceutical carriers as well as a process for preparing a vaccine.

Shirley teaches lactate dehydrogenase enzyme from *E. acervulina*. The enzyme was prepared in NaCl solution (pharmaceutical carrier) and purified from sporozoites, oocysts and merozoites (pages 372, 373 and plate 1A). The protein of Shirley appears to be the same as the claimed protein. The formulation of the

enzyme in NaCl meets the limitations of the claimed process. Characteristics such as immunoreactive determinants and amino acid seq. I.D. No. 2 would be inherent in the enzyme of the prior art. The recitation of "vaccine" is being viewed as intended use of the enzyme. Applicant's use of the open-ended term "comprising" in the claims fails to exclude unrecited steps and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948). Additionally, since the Office does not have the facilities for examining and comparing applicants' protein, vaccine and process with the protein, vaccine and process of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product, vaccine and process and the product, vaccine and process of the prior art (i.e., that the protein, vaccine and process of the prior art does not possess the same material structural and functional characteristics of the claimed protein, vaccine and process). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

5. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Kucera, 1989, Folia Parasitologica 36/4:295-299.

The claims are drawn to an isolated protein represented by SEQ ID NO: 2 from *Eimeria acervulina*.

Kucera teaches the lactate dehydrogenase enzyme from Eimeria acervulina and the isolation and purification of the enzyme (page 296, figure 3). The protein of Kucera appears to be the same as the claimed protein. Characteristics such as immunoreactive determinants and amino acid seq. I.D. No. 2 would be inherent in

the enzyme of the prior art. The recitation of "vaccine" is being viewed as intended use of the enzyme. Applicant's use of the open-ended term "comprising" in the claims fails to exclude unrecited steps and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948). Additionally, since the Office does not have the facilities for examining and comparing applicants' protein, vaccine and process with the protein, vaccine and process of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product, vaccine and process and the product, vaccine and process of the prior art (i.e., that the protein, vaccine and process of the prior art does not possess the same material structural and functional characteristics of the claimed protein, vaccine and process). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

6. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura et al, 1991, Journal of Veterinary Medical Science, 53/6:1101-1103.

The claims are drawn to an isolated protein represented by SEQ ID NO: 2 from *Eimeria acervulina*.

Nakamma et al teach the lactate dehydrogenase enzyme from Eimeria acervulina and the isolation and purification of the enzyme (figure 2, c, d, f). The protein of Nakamura et al appears to be the same as the claimed protein. Characteristics such as immunoreactive determinants and amino acid seq. I.D. No. 2 would be inherent in the enzyme of the prior art. The recitation of "vaccine" is being viewed as intended use of the enzyme. Applicant's use of the open-ended

term "comprising" in the claims fails to exclude unrecited steps and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948). Additionally, since the Office does not have the facilities for examining and comparing applicants' protein, vaccine and process with the protein, vaccine and process of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product, vaccine and process and the product, vaccine and process of the prior art (i.e., that the protein, vaccine and process of the prior art does not possess the same material structural and functional characteristics of the claimed protein, vaccine and process). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

7. With regard to the prior art rejections set forth in paragraphs 4-6, these rejections have been maintained for the reasons of record. Applicant's arguments filed November 25, 2003 have been fully considered but they are not persuasive. Applicants have asserted that the prior art (Shirley, Kucera et al, Nakamura et al) does not disclose or suggest the claimed invention of a protein expressed in vitro, comprising one or more immunoreactive and/or antigenic determinants of Eimeria lactate dehydrogenase (LDH), wherein said isolated protein is found intracellularly in Eimeria; a vaccine for the protection of poultry against Coccidiosis comprising an effective amount of an isolated protein comprising one or more immunoreactive and/or antigenic determinants of Eimeria lactate dehydrogenase, wherein said isolated protein is found intracellularly in Eimeria; and an immunogenic fragment of Eimeria lactate dehydrogenase (LDH), wherein said LDH is immunogenically reactive with antiserum raised against the polypeptide of SEQ ID NO:2. Applicants have asserted that the prior art, at best, discloses a native intact Eimeria LDH protein. Applicants have asserted that the prior art never mentions antigenic or immunogenic features nor does the prior art mention using these proteins as vaccines. Applicants completely disagree with Examiner's statement that the recitation of "vaccine" is an intended use. The vaccine claims stand alone. A

vaccine claim can be clearly patentable, if it is novel, even if the protein itself is anticipated. Applicants have asserted that the prior art fails to discuss a vaccine; thus, it is completely impossible for the prior art to anticipate a "vaccine" claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051/ 1053 (Fed. Cir. 1987). The prior art fails to disclose each element of the present invention as set forth in the claims.

With regard to Applicants' arguments, it is noted that "expressed in vitro" is viewed as a process limitation and does not negate the fact the prior art references disclose the Eimeria LDH. The antigenic or immunogenic features are inherent properties in the disclosed Eimeria. Determination of characteristics, which vary depending on the method of analysis, such as enzymatic activity, or other characteristics must be made by the same method under the same or analogous conditions to show differences that are not otherwise clearly apparent. With regard to Applicants' arguments concerning "vaccine", it is maintained that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

With regard to the 102(b) anticipation art rejections set forth above, the rejections have been maintained for the reasons of record. Applicant's arguments filed July 29, 2004 have been fully considered but they are not persuasive. These arguments have been presented previously and addressed by the Examiner.

8. The prior art rejections have been maintained for the reasons of record. Applicant's arguments filed February 8, 2005 have been fully considered but they are not persuasive. During an interview with Mark Milstead on November 15, 2004, Applicants' representative indicated that applicants may submit evidence that the amino acid sequence of the prior art is not the same as the claimed SEQ ID NO: 2. The response filed February 8, 2005 does not provide any evidence that the

amino acid sequence of the prior art is not the same as the claimed SEQ ID NO: 2. Applicants have asserted that the prior art fails to disclose or suggest a protein expressed *in vitro* comprising an isolated protein found intracellularly in Eimeria and is represented by the amino acid sequence shown in SEQ ID NO: 2 and a vaccine for the protection of poultry against Coccidiosis comprising an effective amount of an isolated protein as described above. Applicants have asserted that at best the references disclose a native intact Eimeria LDH protein and that none of the references mention using these proteins as vaccines. Applicants have asserted that a vaccine claims can be clearly patentable, it is novel, even if the protein itself is anticipated and that the references fail to anticipate a "vaccine".

However, as previously stated the recitation of "expressed in vitro" is viewed as a process limitation and does not negate the fact the prior art references disclose the *Eimeria* LDH, the specifically claimed species of *Eimeria acervulina* is also disclosed. Characteristics such as the amino acid SEQ ID NO: 2 would be inherent in the enzyme of the prior art. Determination of characteristics, which vary depending on the method of analysis, such as enzymatic activity, amino acid sequence or other characteristics must be made by the same method under the same or analogous conditions to show differences that are not otherwise clearly apparent. With regard to Applicants' arguments concerning "vaccine", it is maintained that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative

difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicants' have amended the claims to delete the recitation of "Eimeria lactate dehydrogenase (LDH)". However, the specification teaches that "...this protein is found intracellularly in Eimeria and it appears to contain high sequence homology with known heterologous lactate dehydrogenases (LDH). Thus, the invention provides a protein having one or more immunoreactive and/or antigenic determinants of Eimeria lactate dehydrogenase, which has a monomeric molecular weight of about 37 kD. More specifically the lactate dehydrogenase is derived from *Eimeria acervulina*." (specification p. 6) "More particularly, this invention provides proteins possessing LDH activity, or immunogenically active parts thereof, which have the amino acid sequence shown in SEQ ID NO. 2 and their biologically functional equivalents or variants." (specification p. 7) Even though Applicants have deleted a specific functional characteristic of the protein (lactate dehydrogenase activity), the specification teaches that claimed protein represented by the amino acid sequence shown in SEQ ID NO: 2 has LDH activity. Therefore, the prior art discloses the claimed invention.

With regard to Applicants' arguments regarding inherency, MPEP 2112.01 states that "[W]here the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed.

Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

With regard to Applicants' assertion that a vaccine claim can be clearly patentable, it is novel, even if the protein itself is anticipated and that the references fail to anticipate a vaccine". It is noted that the MPEP 2112 states that "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Since the Office does not have the facilities for examining and comparing applicants' protein and vaccine with the protein and vaccine of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and vaccine and the product and vaccine of the prior art (i.e., that the protein and vaccine of the prior art does not possess the same material structural and functional characteristics of the claimed protein and vaccine). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

9. No claims are allowed.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM

April 21, 2005